IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

ANNE JEAN CANNON, deceased, and ESTATE OF ANNE JEAN CANNON by and through JOHN CANNON and FRANCIS CANNON *Plaintiffs*	:	**CIVIL ACTION** **NO. 21-1451**
v.	:	
WATERMARK RETIREMENT COMMUNITIES, INC. d/b/a BLUE BELL PLACE, *et al.* *Defendants*	:	

NITZA I. QUIÑONES ALEJANDRO, J. JULY 19, 2021

MEMORANDUM OPINION[1]

INTRODUCTION

Plaintiffs, representing the Estate of Anne Jean Cannon, filed this civil action against Defendants, the business entities that own and operate the Blue Bell Place senior living community where Plaintiff Anne Jean Cannon ("Cannon") lived during the events underlying this case. In the amended complaint, Plaintiffs assert various claims, including claims of negligence, negligence *per se*, reckless and outrageous conduct, wrongful death and survival action, all stemming from the alleged abuse and eventual death of Cannon at Blue Bell Place. [ECF 9]. Defendants moved to dismiss the amended complaint pursuant to Federal Rules of Civil Procedure ("Rule") 12(b)(1) and (b)(6), for a lack of subject-matter jurisdiction and a failure to state a claim on which relief can be granted. Specifically, Defendants contend that they are entitled to immunity from suit under the Public Readiness and Emergency Preparedness Act ("PREP Act"), 42 U.S.C. §§ 247d-6d,

[1] This Memorandum Opinion corresponds with this Court's May 28, 2021 Order denying Defendants' motion to dismiss, [*see* ECF 20], in which no opinion was issued. In light of Defendants' interlocutory appeal to the United States Court of Appeals for the District of Columbia Circuit, this Court authors this Memorandum Opinion to supplement the Order.

247d-6e. Plaintiffs oppose the motion, arguing that Defendants are not entitled to immunity. For the reasons set forth herein, at this stage of litigation, this Court agrees with Plaintiffs.

BACKGROUND

When ruling on a motion to dismiss, this Court must accept as true all the factual allegations in Plaintiff's complaint and construe the complaint in the light most favorable to the Plaintiff. *Fowler v. UMPC Shadyside*, 578 F.3d 203, 210-11 (3d Cir. 2009) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 677 (2009)). The relevant allegations in Plaintiff's amended complaint are summarized as follows:

> Blue Bell Place is a senior living community owned and operated by Defendants. In January 2020, Cannon became a resident of Blue Bell Place. Plaintiffs allege that shortly after she began her residency, they noticed a series of instances in which Cannon's basic hygiene needs were not being met, she received inappropriate care, and suffered physical abuse from employees at Blue Bell Place. When the COVID-19 Pandemic began affecting the United States, Blue Bell Place prohibited visitors in accordance with the restrictions and regulations imposed by local government.
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> On or around April 20, 2020, Cannon tested positive for COVID-19, although she showed no signs of illness and was "completely asymptomatic." Two days later, on April 22, 2020, a nurse assistant at Blue Bell Place called Cannon's son, who had Cannon's Medical Power of Attorney, and stated that she wanted to commence treating Cannon with an experimental treatment involving the drugs hydroxychloroquine and doxycycline, for five days. Plaintiffs contend that Cannon's family was concerned about the experimental drug because it was not FDA-approved and had a history of causing harmful reactions in patients with heart issues, which Cannon had. Cannon's son informed the nurse assistant that he did not consent to his mother receiving the experimental treatment.
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> Plaintiffs contend that the experimental use of hydroxychloroquine and doxycycline, at that time, was not permitted to be administered outside of a hospital and was only authorized to be used if the patient was symptomatic and ineligible for a clinical trial. Despite the lack of consent, the staff at Blue Bell Place administered the experimental treatment to Cannon for five days, beginning on April 22, 2020, against Cannon's wishes and the directive of her son. Following the administration of the treatment, Cannon fell ill and her condition deteriorated. On May 4, 2020, Cannon passed away, reportedly due to "a cardiac event and COVID-19."

LEGAL STANDARD OF REVIEW

Rule 12(b)(6) permits a court to grant a motion to dismiss an action if the complaint "fail[s] to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). When considering a Rule 12(b)(6) motion, a court "must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." *Fowler*, 578 F.3d at 210-11 (citing *Iqbal*, 556 U.S. at 677). The court must determine whether the plaintiff has pled facts sufficient to show a plausible entitlement to relief. *Fowler*, 578 F.3d at 211. The complaint must do more than merely allege a plaintiff's entitlement to relief—it must "show such an entitlement with its facts." *Id*. (citations omitted). The plaintiff "must allege facts sufficient to 'nudge [his or her] claims across the line from conceivable to plausible.'" *Phillips v. Cty. of Allegheny*, 515 F.3d 224, 234 (3d Cir. 2008) (quoting *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Mere "labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Twombly*, 550 U.S. at 555. After construing the complaint in the light most favorable to the plaintiff, if the court finds that the plaintiff could not be entitled to relief, it can dismiss the claim. *Fowler*, 578 F.3d at 210.

DISCUSSION

The PREP Act provides, *inter alia*, that "a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if [the Secretary of Health and Human Services has issued a declaration permitting the administration of that covered countermeasure]." 42 U.S.C. § 247d-6d(a)(1). Assuming, for the purposes of this Opinion only, that Blue Bell Place is a "covered person" under the PREP Act,[2] the issue before this Court is whether Blue Bell Place administered a "covered countermeasure"

[2] Plaintiffs also dispute whether Blue Bell Place is a covered person/entity under the PREP Act. However, this dispute is not determinative of the outcome of this motion; thus, this Court will assume, for the purposes of this Opinion, that Blue Bell Place is a covered person.

when it administered the experimental treatment to Cannon, since the PREP Act affords immunity only for "claims caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure[.]" *Id*.

I. Covered Countermeasure

Defendants argue that the experimental administration of hydroxychloroquine and doxycycline is a covered countermeasure because the Secretary of Health and Human Services ("Secretary") issued a declaration on March 10, 2020 (the "March 10th Declaration") defining "medical countermeasures against COVID-19," 85 Fed. Reg. 15198, 15201, as "any antiviral, any other drug, any biologic, any diagnostic, [or] any other device . . . used to treat, diagnose, cure, prevent, or mitigate COVID-19[,]" *id*. at 15202, that are either "'qualified pandemic or epidemic products,' or 'security countermeasures,' or drugs, biological products, or devices *authorized for investigational or emergency use*, as those terms are defined in the PREP Act, the [Federal Food, Drug, and Cosmetics] Act, and the Public Health Service Act." [3] *Id* (indicating that, *in addition* to the requirement that an antiviral, drug, or device is being used to treat, diagnose, cure, prevent, or mitigate COVID-19, the antiviral, drug, or device *also* "must be 'qualified pandemic or epidemic products,' or 'security countermeasures,' or drugs, biological products, or devices authorized for investigational or emergency use").

Defendants contend that the experimental treatment it administered to Cannon was a drug regimen that was authorized for emergency use under the Federal Food, Drug, and Cosmetic Act

[3] The phrasing structure of this definition was changed in the Secretary's amendment declaration issued on December 9, 2020 (the "December 9th Declaration"), but all substantive portions relevant in this matter (that would apply to the treatment in question) remained unchanged. One notable change that reflects the segments of the March 10th Declaration that this Court emphasized above is that the second requirement is restated as follows: "To be a Covered Countermeasure under the [December 9th] Declaration, a product must also meet 42 U.S.C. 247d-6d(i)(1)'s definition of 'Covered Countermeasure.'" 85 Fed. Reg. 79196. The referenced statute then provides that a drug or product (as opposed to a "qualified pandemic or epidemic product, security countermeasure, or respiratory protective device") can only be a covered countermeasure if it "is authorized for emergency use in accordance with section 564, 564A, or 564B of the [FDCA]." 42 U.S.C. 247d-6d(i)(1)(C).

("FDCA") by the Food and Drug Administration ("FDA") on March 28, 2020 and, thus, constitutes a covered countermeasure. *See* Def. Br., ECF 11, at 27, 143-151. In response, Plaintiffs directed this Court to the "fine print" of the FDA's March 28, 2020 letter granting emergency use authorization for the use of hydroxychloroquine sulfate ("March 28th EUA"). *See* Am. Compl., ECF 9, Ex. B, 22-30 and Def. Br., Ex. M, 143-51.

In relevant part, the March 28th EUA provides: "the scope of this authorization is limited to chloroquine phosphate and hydroxychloroquine sulfate for the treatment of COVID-19, as described in this section." *Id*. at 146 and at 25. The scope section (Section II) describes the limited scope of the authorization of hydroxychloroquine sulfate as follows:

> [The FDA is] authorizing use of the following hydroxychloroquine sulfate product . . . for response to the COVID-19 pandemic: [(1) a form of hydroxychloroquine sulfate that is already] approved by FDA for other uses[; (2) t]he hydroxychloroquine sulfate must be administered by a healthcare provider pursuant to a valid prescription[; and (3) t]he hydroxychloroquine sulfate **may only be used to treat adult and adolescent patients who weigh 50 kg or more, hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible**.

Id. at 26 and at 147 (emphasis added).

In the amended complaint, Plaintiffs alleged that Defendants used hydroxychloroquine sulfate to treat Cannon (1) while she was at Blue Bell Place (a senior living community) and *not* in a hospital, as Ms. Cannon was *never hospitalized* for her asymptomatic COVID-19, (2) before it had been determined that Ms. Cannon was not eligible for a clinical trial or that her participation in a clinical trial was not feasible, and (3) without the consent of either Cannon or the person with her Medical Power of Attorney.

Accepting Plaintiffs' allegations as true, as this Court must at this motion to dismiss stage of the proceedings, Defendants' administration of hydroxychloroquine sulfate does not fall within the clear, explicit, and limited scope of the drug's FDA emergency use authorization. Therefore, based on these allegations, the administration of the treatment *as Defendants used it* cannot be

considered a covered countermeasure because it was not "authorized for investigational or emergency use, as those terms are defined in the [FDCA,]" as required by the PREP Act. 85 Fed. Reg. 15202. Accordingly, Defendants' motion to dismiss is denied.

Nevertheless, Defendants also argue that PREP Act immunity also applies to the "misuse" of a covered countermeasure and, thus, even if Defendants misused the hydroxychloroquine sulfate, they should be afforded immunity. This argument is, however, misguided. The section of the December 9th Declaration to which Defendants cite for this contention is 85 Fed. Reg. 79197, which amended Section IX on "Administration of Covered Countermeasures", *not* Section VI which *defines* Covered Countermeasures. Specifically, Section 79197 defines what the "administration" of covered countermeasures entails. Notably, this amendment does not have any bearing on the definition of covered countermeasures itself, or the scope thereof. The cited amendment *does* establish that a covered person or entity's deliberate choice "not [to] administer[] a Covered Countermeasure" does constitute "administration" of a covered countermeasure under the statute; however, that factual scenario is not present here. Defendants did not choose *not* to administer a treatment to Cannon; precisely the opposite, they chose to take an affirmative action (as opposed to an omission) and administer a treatment to Cannon without her consent. The cited amendment says nothing about "misuse" of covered countermeasures, it only addresses the non-use or omission of use as a conscious decision by a covered person or entity. Thus, Section 79197 does not establish what Defendants suggest. This Court finds this argument is without merit.

Defendants also cite to Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision issued by the Office of General Counsel for the Secretary on January 8, 2021 ("AO 21-01") to support their contention that immunity applies to the misuse of a covered countermeasure. AO 21-01, which explicitly clarifies that it "sets forth the current views of the Office of the General Counsel[,] is not a final agency action or a final order[, and] does not have the force or effect of law[,]" addressed the narrow question of "whether

the PREP Act applies where a covered person declined to use a covered countermeasure when it arguably ought to have been used." U.S. Dep't of Health & Human Services, Office of the Secretary, General Counsel, Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision (Jan. 8, 2021) at p. 1, 5. As with the declaration amendment Defendants cited (85 Fed. Reg. 79197), the advisory opinion (AO 21-01) does not actually speak to the *misuse* of covered countermeasures, it only addresses "the use or non-use of covered countermeasures[.]" *Id*. at p. 1. As such, AO 21-01 also does not support or establish Defendant's contention.

Furthermore, even if Defendants could point to some authoritative or persuasive source establishing that the misuse of covered countermeasures is protected, such a source would be inapplicable to this case. Defendants did not "misuse" a covered countermeasure because, in order to misuse a covered countermeasure, the treatment in question must first satisfy the definition of a covered countermeasure, which, as explained above, Defendants' administration of treatment to Cannon does not.

II. PREP Act Safe Harbor Provision

Alternatively, Defendants argue that even if the treatment was not a covered countermeasure, they are entitled to immunity under the PREP Act's "'safe harbor' provision set forth in 42 U.S.C. § 247d-6d(a)(4)(B)[.]" Def. Reply., ECF 15, at 5. This argument is also misguided. Section 247d-6d(a)(4)(B) provides that "the scope of immunity includes circumstances in which [a covered] countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C)." Paragraph (3)(C) sets forth two conditions; *to wit*: "the countermeasure was administered to or used by an individual who—(i) was in a population specified by the declaration; and (ii) at the time of administration physically present in a geographic area specified by the

declaration or had a connection to such area specified in the declaration." 42 U.S.C. § 247d-6d(a)(3)(C).

Defendants are correct that these two provisions together provide immunity for a covered entity that "reasonably could have believed" that the countermeasure it was administering was (1) being administered to and by the proper populations specified in the Secretary's declaration and (2) being administered within a proper geographic area specified in the Secretary's declaration, even if the countermeasure did not actually satisfy those conditions.[4] However, these provisions do not afford Defendants immunity at this stage of the proceedings where this Court must construe the facts in Plaintiffs' favor. Construing the facts alleged accordingly, it would *not* have been reasonable for Defendants to believe that their agents' administration of hydroxychloroquine sulfate was being administered to a person who is part of a specified population. The very document that authorized hydroxychloroquine sulfate for emergency use *explicitly* specified the required populations to which use of the treatment was limited; *to wit*: the drug needed to be "administered by a healthcare provider pursuant to a valid prescription" and administered to "adult and adolescent patients who weigh 50 kg or more hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible." Def. Br., Ex. M, 147 and Am. Compl., Ex. B, 26. It is not reasonable for Defendants to have believed that Cannon "was in a population specified by the declaration," 42 U.S.C. § 247d-6d(a)(3)(C), when the specified population was unambiguous and Cannon indisputably did not fall within that specified population (*i.e.*, she was not hospitalized with COVID-19, nor had it been determined that she was not eligible for any

[4] This interpretation is consistent with the interpretation of General Counsel for the Secretary, cited by Defendants: "a person or entity that otherwise meets the requirements for PREP Act immunity will not lose that immunity—even if the product is *not* a covered countermeasure—if that person or entity reasonably could have believed that the product was a covered countermeasure." U.S. Dep't of Health & Human Services, Office of the Secretary, General Counsel, Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration Under the Act (April 17, 2021, as modified on May 19, 2020) at p. 4.

available clinical trials). Therefore, Defendants are also not entitled to immunity under § 247d-6d(a)(4)(B).

CONCLUSION

For the reasons set forth herein, this Court finds that Defendants are not entitled to immunity from suit under the PREP Act, at this stage in litigation. Accordingly, Defendants' motion to dismiss is denied.

NITZA I. QUIÑONES ALEJANDRO, U.S.D.C. J.